TESTIMONY OF MARK A. BEHRENS, ESQ.
SENIOR ASSOCIATE
CROWELL & MORING LLP
WASHINGTON, D. C.

BEFORE THE SUBCOMMITTEE ON
TELECOMMUNICATIONS, TRADE AND CONSUMER PROTECTION
OF THE HOUSE COMMERCE COMMITTEE
UNITED STATES HOUSE OF REPRESENTATIVES

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EXECUTIVE SUMMARY OF TESTIMONY OF MARK A. BEHBENS. ESQ.

Approximately 7.5 million Americans depend on the availability of implantable medical devices, such as pacemakers, heart valves, artificial blood vessels, and hip and knee joints. The availability of these devices is critically threatened, however, because suppliers have ceased supplying raw materials and component parts to medical implant manufacturers. Suppliers have found that the risks and costs of responding to litigation related to medical implants far exceeds potential sales revenues, even though courts are not finding suppliers liable.

Federal biomaterials access assurance legislation would help prevent a public health crisis by limiting the liability of biomaterials suppliers to instances in which the supplier failed to meet contractual specifications. In addition, it would establish a procedure ***to ensure*** that suppliers can avoid litigation without incurring heavy legal costs. The legislation would protect patient health, maintain the competitiveness of the medical device industry, and preserve U.S. jobs.

The legislation would not in any way diminish the existing liability of implantable medical device manufacturers. If the legislation becomes law, ***any*** party who makes a defective implant will still be fully liable.

Federal biomaterials access assurance legislation is needed. The subject has been the focus of careful examination in hearings spanning several years and enjoys strong bipartisan support. The situation is urgent. Congress should adopt this important, pro-patient legislation now.

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Mr. Chairman, Members of the Committee, thank you for inviting me to testily today regarding the emerging public health crisis caused by the inability of medical device manufacturers to purchase supplies of basic raw materials (biomaterials) and components needed to make life-saving and life-enhancing implants. My name is Mark Behrens. I am a senior associate in the Washington, DC law firm of Crowell & Moring LLP.

THE EMERGING BIOMATERIALS AVAILABILITY CRISIS

Approximately 7.5 million Americans depend on the availability of implantable medical devices, such as pacemakers, heart valves, artificial blood vessels, shunts, and hip and knee joints. The availability of these devices is threatened, however, because suppliers have ceased supplying raw materials and component parts to medical implant manufacturers. The nature of the problem has led Senator Lieberman to observe that Americans are facing a "public health time bomb." Senator Lieberman and many in the House, such as Representative Gekas, were quick to recognize the need for federal biomaterials access assurance legislation.

Suppliers of biomaterials and component parts used to make medical devices are reluctant to sell to medical device manufacturers because, under current litigation practice, the suppliers are routinely sued with device manufacturers in actions alleging inadequate design and testing of the medical device and inadequate warnings related to the use of the medical device. The raw

materials and component parts, however, are not designed or manufactured specifically for use in medical devices. Mostly, they are used in a variety of nonmedical products. Furthermore, the suppliers do not design, produce or test medical devices. That is the responsibility of the medical device manufacturer under regulations promulgated by the Federal Food and Drug Administration. Consequently, courts are not finding suppliers liable.

Nevertheless, the costs to suppliers of successfully defending themselves in product liability lawsuits far exceed the expected return from supplying the biomaterials. There may be only pennies of a raw material in a medical device, but successful defense of a single product liability lawsuit could cost a company several hundred thousand dollars. As a result, supplying materials for medical devices is a very small portion of the suppliers' businesses and is foregone to avoid the cost of (successfully) defending liability suits.

Dr. Arnoff, who is testifying before the Committee today, will unveil a sound and thorough study on the current biomaterials availability problem. His findings are compelling and show that significant shortages of essential biomaterials will occur as existing stockpiles are exhausted. Patients will suffer.

These patients include some who appear today to testify before the Committee. Others including Thomas Deuschle, a private citizen from Liberty, Missouri, and Dr. Steven Gunther, Chief Resident of Orthopaedics at George Washington University Hospital in Washington, D.C., testified on March 4, 1997, before the Senate Commerce Committee.

Thomas Deuschle told about his daughter, Emma, who was born in 1990 with a hole in her heart, a condition known as VDS. Emma was born with an extremely low birth weight and was unable to gain weight, because her heart condition artificially elevated her metabolic rate. After several months, Emma underwent open heart surgery to have a Dacron@ polyester patch placed over the hole in her heart. Today, Emma is a healthy, happy six year old. Her father testified that it would have been a personal tragedy if the Dacron@ patch had not been available for Emma and urged passage of federal biomaterials access assurance legislation. DuPont, the manufacturer of Dacron@ polyester, has indicated it will no longer supply that material to manufacturers of medical devices.

Dr. Steven Gunther spoke as a private citizen and patient advocate. In October 1996, he sustained second- and third-degree burns over sixty-five percent of his body. The severity and scope of his burns made the threat of infection and dehydration deadly possibilities. Shortly after Dr. Gunther sustained his injuries, his legs were wrapped in a new medical product known as Integra. Integra is a two layer "artificial skin" made from bovine collagen and silicone that prevents both infection and fluid and electrolyte loss. The Integra effectively "masked" the burns on his legs, allowing his physiological defense mechanisms to focus on those parts of his body that did not receive Integra. As a result, the healing process was hastened exponentially. Dr. Gunther has now resumed his Orthopaedic practice full-time. He called for passage of federal biomaterials availability legislation.

A PENNY OF PLASTIC AND A POUND OF LEGAL COSTS– HOW THE BIOMATERIALS AVAILABILITY CRISIS STARTED

Until recent years, E.I. du Pont de Nemours and Co. (DuPont) was a major supplier of key materials used to manufacture implantable medical devices. These materials are made for general applications and are not made specifically for use in implants. In fact, the medical implant market represents a tiny portion of total raw materials sales -- in some cases the percentage is almost invisible.

Polytetraflouroethylene (PTFE) resin is one example. DuPont uses the trademark "Teflon@" together with the polymer name to identify its brand of the material. DuPont Teflon@ PTFE is famous as a nonstick, slippery, solid material which has a multiplicity of uses. It may be part of the finish on kitchen skillets you have at home. DuPont Teflon@ PTFE is also used in a variety of implants ranging from ventilation tubes for infants to coatings for sutures. The medical device market, however, accounts for less than one-half of one percent of total PTFE sales.

One of the companies that purchased DuPont Teflon@ PTFE was Vitek, Inc., a manufacturer of temporomandibular joint (jaw) implants. As a raw material supplier, DuPont had no control over the design, manufacture, or sale of Vitek's TMJ implant.

Vitek went bankrupt in 1990, because of mass litigation involving its implant. As the "deep pocket," DuPont was left to confront numerous lawsuits. A total of approximately 1,605 Vitek TMJ implant recipients (plus their spouses) filed 651 lawsuits against DuPont in 41 states and Canada.

DuPont's defense of the TMJ Implant Litigation has been enormously successful. DuPont has won every TMJ case that has been decided to final judgment by the courts. The company's raw material supplier defense has been affirmed by all seven U.S. Courts of Appeal that have ruled on the issue. Three of these federal appellate courts have ruled for DuPont twice; another has ruled for DuPont three times in a row.

The company also has prevailed at the federal district court level. Most notably, in January 1995, U.S. District Court Judge Paul Magnuson granted summary judgment for DuPont in a consolidated case involving 280 federal TMJ cases and ordered that any future federal TMJ cases are to be automatically dismissed. This order was affirmed by the Eighth Circuit Court of Appeals.

In addition, DuPont has prevailed in all state appeals courts that have considered its raw material supplier defense. DuPont's dismissal from the Vitek TMJ Implant Litigation has been upheld by state appellate courts in Arizona, California, Colorado, Louisiana, New Mexico, Oregon, Texas, and Wisconsin.

The decision of the Wisconsin Court of Appeals in *Westphal v. **E.I. du Pont de Nemours and Co., 531*** N.W.2d 386 (Wis. App. 1995), review denied, 537 N.W.2d 571 (Wis. 1995), is illustrative. The Court of Appeals found that,

> As a component supplier, DuPont had no control over the design or manufacture of Vitek's TMJ implant. Vitek's TMJ implant is a highly specialized product. Public policy is best served by shifting liability from DuPont in this situation.

531 N.W.2d 386 at 391

Similarly, the Colorado Court of Appeals wrote in Bond *v.* E.I. *du Pont* de Nemours and Co., 868 P.2d 1114, 1120 (Colo. App. 1993) that,

> [T]he social utility of permitting DuPont to grant relatively unrestrained access to purchasers of its product [Teflon@ PTFE] is high, especially here, because it encourages development of new products in the medical field and does not unnecessarily inhibit technological advances.

At this time, a defense judgment or dismissal in favor of DuPont has been entered on ninety-eight percent of the claims. DuPont expects that the remaining two percent also will be dismissed.

These wins, however, represent a very costly victory. DuPont's Teflon@ PTFE sales to Vitek totaled only a few hundred dollars per year (about $0.05 worth of Teflon@ PTFE per implant). Yet, the Vitek TMJ Implant Litigation has cost DuPont an estimated $8 million per year in legal costs, according to a 1993 study by Dr. Aronoff. Apart from direct legal costs, these suits have drained "person power" away from other more productive tasks, such as research and development.

What would any reasonable person do in these circumstances? As a result of its Vitek TMJ Implant Litigation experience, DuPont announced in 1993 that it would no longer supply materials like Teflon@ PTFE or Dacron@ polyester for use in medical implants. Other major suppliers have made similar announcements

These were rational and necessary business decisions. Materials like Teflon@ PTFE are sold for a wide variety of general applications. The medical device market represents only a minuscule portion of total sales. And, the

potential cost of responding to litigation involving finished implants that the company does not design, manufacture or control remains staggering, even though courts are not finding suppliers like DuPont liable.

FEDERAL LEGISLATION IS URGENTLY NEEDED

Federal product liability reform legislation that includes biomaterials access assurance legislation is urgently needed. I have highlighted some of the numerous witnesses who have testified in support of biomaterials availability legislation. The extensive hearings before House and Senate Committees provide in-depth support.

Unless Congress acts, adverse effects on patients, doctors and the medical device industry can be expected. These effects run counter to the best interests of this Nation.

First, as Dr. Arnoff's 1997 report makes clear, when stockpiles of unique materials are used up, some implants will no longer be available. Doctors will have fewer choices available to provide the best treatment for patients. Patients will suffer.

Second, the competitiveness of the medical device industry is undermined when device manufacturers must divert resources away from research and development to "find" new sources of materials. Innovation is also frustrated when new product efforts must be confined to available sources of raw material supplies.

One must remember that the leadership position of the U.S. in the medical device area relies heavily on start-up and "small cap" companies. These companies, in particular, are hurt by the lack of biomaterials availability. While some very financially powerful companies can obtain supplies of some (but not all) biomaterials by entering into restrictive indemnification agreements with suppliers, this is simply not an option for many smaller companies.

Third, although sales of raw materials for medical implant uses represent a small portion of all raw materials sales, there is nevertheless a market need that exists. Federal biomaterials legislation would help stop the needless exportation of jobs to foreign countries by allowing market needs to be met by sound U.S. companies.

Federal biomaterials access assurance legislation would protect patient health, maintain the competitiveness of the medical device industry, and preserve U.S. jobs by placing rational limits on the liability of biomaterials and component suppliers. The legislation would hold suppliers liable for failure to meet contractual specifications. In addition, it would establish a procedure to ensure that suppliers can avoid litigation without incurring heavy legal costs.

The legislation would not in any way diminish the existing liability of implantable medical device manufacturers. If the legislation becomes law, any party who makes a defective implant will still be fully liable.

To address a very specific and limited political concern that was raised with respect to legislation which passed out of the House and Senate last Congress,

legislation currently being considered specifically excludes silicone breast implant cases from coverage.

"FRAUDULENT SUPPLIER" ARGUMENT IS BASELESS

Recently, the Association of Trial Lawyers of America (ATLA) and its allied professional consumer groups have argued that federal biomaterials access assurance legislation would protect "fraudulent suppliers" from liability (i.e., a supplier who knows that is raw material (biomaterial) could cause harm if implanted, but fails to inform the device manufacturer). This argument ignores the reality of the biomaterials availability problem and the strong public policy supporting the need for federal legislation.

Basically, opponents are arguing that, under current liability law, they get to fly "first class" now and they do not want to fly "coach." The problem is that, when current stockpiles of biomaterials are exhausted, there will not be any "plane" to fly. Certain devices will no longer be available at all in the United States.

Consequently, U.S. citizens will have to travel to foreign countries to obtain certain devices, and have no meaningful legal recourse if something goes wrong. Or, manufacturers of medical devices will have to purchase supplies from foreign manufacturers who have no assets or place of business in this country. In this situation, a plaintiff will have no case against a supplier of raw materials in any situation, even if the raw material supplier violated contractual requirements. See *Asahi Metal Industry Co., Ltd. v. Superior Court of California, 480* U.S. 102

(1987) (holding that a foreign manufacturer did not purposefully avail itself of the U.S. market merely because it was foreseeable that its product would be sold in the U.S.; accordingly, the manufacturer could not be subject to the jurisdiction of U.S. courts).

CONCLUSION

Federal biomaterials access assurance legislation is urgently needed. The subject has been the focus of careful examination in extensive hearings spanning several years and enjoys strong bipartisan support. Congress should adopt this important, pro-patient legislation now.

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